Letter

ECMO

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The framework proposed by Miké and her colleagues for the evaluation of medical interventions like neonatal Extra-Corporeal Membrane Oxygenation (ECMO) is practicable.

Because of the paucity of reliable evidence about the clinical and cost-effectiveness of this technology, we are presently co-ordinating a trial comparing optimal conventional ventilatory management with a policy of transfer for consideration of ECMO support for neonates with acute respiratory failure in the UK. We are gratified to see how well this trial fits into Miké *et al*'s proposed framework.

The trial is designed as a straightforward, parallel group, randomized controlled trial. To ensure balance in the principal prognostic variables, minimization by ECMO centre, disease category, referral hospital, and initial disease severity is part of the central telephone randomization programme. The primary analysis will be by 'intention to treat', with pre-specified secondary analyses stratified by, for example, the disease category. The number of cases treated in an ECMO centre is being recorded to address the issue of a 'learning curve'.

Paediatricians and paediatric surgeons in the UK have recognized the importance of collaboration. Over 70 clinical centres are participating and, at present, all four centres offering ECMO in the UK have a policy of providing ECMO support to trial-eligible babies in the context of the trial only.

Parents in participating hospitals are asked for assent to their baby's recruitment into the trial when certain eligibility criteria are met, although there may be an approach to discuss the possibility of trial entry at an earlier stage. The written information which the parents are given at this and at later points in time have been discussed with members of relevant 'consumer' groups concerned with perinatal issues.

The principal outcome measure is not just short term survival but the baby's status at one year of age in terms of survival without severe disability as assessed at a home visit by a developmental paediatrician. In the multidisciplinary trial team, social scientists (particularly health economists) are considering the economic and socio-psychological aspects of the two policies being compared, and of participation in the trial.

The trial is already being seen within the UK as an exemplar for technology assessment. Recruitment opened in January 1993. After 14 months over 70 babies have been entered into the trial, making this the largest ever randomized trial of neonatal ECMO. The aim is to recruit 300 babies over three years. Only in this way will the important questions about the effectiveness of this technology be answered.

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News and notes

Ethical review of clinical research

A conference to review the ethics of clinical research – a training conference for ethics committee members – will be held at Robinson College, Cambridge University from 25–27 September this year.

Topics will include: Research protocols and the review process; Regulatory issues; Risks and benefits; Informed consent, and Future directions of ethical review.

For further information please contact: Dr Annette Garnett, Conference Administrator, Simbec Research Limited, Merthyr Tydfil Industrial Park, Merthyr Tydfil, Mid Glamorgan, CF48 4DR.